In the depressed and anxious patient

## See Improvement



## In The First Week...

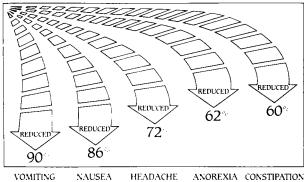
## And The Weeks That Follow

74% of patients experienced improved sleep after the first *h.s.* dose<sup>1</sup>

First week reduction in somatic symptoms<sup>1</sup>



Percentage of Reduction in Individual Somatic Symptoms During First Week of Limbitrol Therapy\*



NAUSEA

\*Patients often presented with more than one somatic symptom.

## Each tablet contains 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)

Each tablet contains 10 mg chlordiazepoxide and 25 mg amitriptyline as the hydrochloride salty



Caution patients about the combined effects of Limbitrol with alcohol or other CNS depressants and about activities requiring complete mental alertness, such as operating machinery or driving a car. In general, limit dosage to the lowest effective amount in elderly patients.



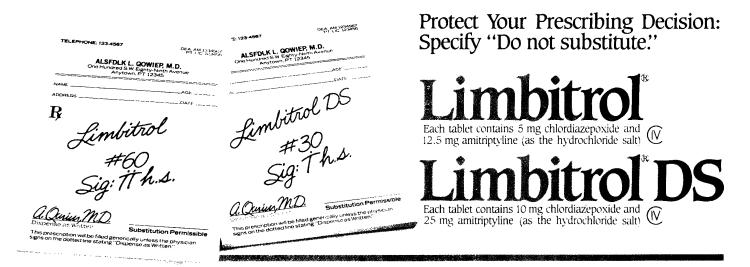
Please see summary of product information on following page.

## In moderate depression and anxiety

74% of patients experienced improved sleep after the first *h.s.* dose<sup>1</sup>

First week improvement in somatic symptoms<sup>1</sup>

50% greater improvement with Limbitrol in the first week than with amitriptyline alone<sup>2</sup>



References: 1. Data on file, Hoffmann 1.a Roche, Inc., Nutley, NJ. 2. Feighner VP, et al: Psychopharma-cology 61:217-225, Mar 22, 1979.

## Limbitrol\* 6

Tranquilizer-Antidepressant

Before prescribing, please consult complete product information, a summary of which follows:

**Contraindications:** Known hypersensitivity to benzodiazepines or tricyclic antidepressants; concomitant use with MAOIs or within 14 days of monoamine oxidase inhibitors (then initiate cautiously, gradually increasing dosage until optimal response is achieved): during acute recovery phase following myocardial infarction.

**Warnings:** Use with caution in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur when used with anticholinergics. Closely supervise cardiovascular patients. Arrhythmias, sinus tachycardia, prolongation of conduction time, myocardial infarction and stroke reported with tricyclic antidepressants, especially in high doses. Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations. Consider possibility of pregnancy when instituting therapy.

Withdrawal symptoms of the barbiturate type have occurred after discontinuation of benzodiazepines (see Drug Abuse and Dependence).

Precautions: Use cautiously in patients with a history of seizures, in hyperthyroid patients, those on thyroid medication, patients with impaired renal or hepatic function. Because of suicidal ideation in depressed patients, do not permit easy access to large quantities of drug. Periodic liver function tests and blood counts recommended during prolonged treatment. Amitriptyline may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady-state concentrations of the tricyclic drugs. Use of Limbitrol with other psychotropic drugs has not been evaluated; sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Should not be taken during the nursing period or by children under 12. In elderly and debilitated, limit to smallest effective dosage to preclude ataxia, eversedation, confusion or anticholinergic effects. Inform patients to consult physician before increasing dose or abruptly discontinuing this drug.

Adverse Reactions: Most frequent: drowsiness, dry mouth, constipation, blurred vision, dizzi ness, bloating. Less frequent: vivid dreams, impotence, tremor, confusion, nasal congestion. Rare: granulocytopenia, jaundice, hepatic dysfunction. Others: many symptoms associated with depression including anorexia, fatigue, weakness, restlessness, lethargy.

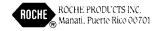
Adverse reactions not reported with Limbittol but reported with one or both components or

Adverse reactions not reported with Limbitrol but reported with one or both components or closely related drugs: Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke. Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania, increased or decreased libido. Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extra pyramidal symptoms, syncope, changes in EEG patterns. Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract. Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus. Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia. Gastrointesti nal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue. Endocrine: Testicular swelling, gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion. Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alepecia, parotid swelling.

Drug Abuse and Dependence: Withdrawal symptoms similar to those noted with barbiturates and alcohol have occurred following abrupt discontinuance of chlordiazepoxide: more severe seen after excessive doses over extended periods; milder after taking continuously at therapeutic levels for several months. Withdrawal symptoms also reported with abrupt amitriptyline discontinuation. Therefore, after extended therapy, avoid abrupt discontinuation and taper dosage. Carefully supervise addiction-prone individuals because of predisposition to habituation and dependence.

**Overdosage:** Immediately hospitalize patient. Treat symptomatically and supportively. I.V. administration of 1 to 3 mg physostigmine salicylate may reverse symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

**How Supplied:** *Double strength (DS) Tablets,* white, film coated, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and *Tablets,* blue, film-coated, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)—bottles of 100 and 500; Tel-E-Dose\* packages of 100; Prescription Paks of 50.



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\*CAPOTEN® (captopril tablets) may be used as initial therapy only for patients with normal renal function in whom the risk of neutropenia/agranulocytosis is relatively low (1 out of over 8,600 in clinical trials). Use special precautions in patients with impaired renal function, collagen vascular disorders, or those exposed to other drugs known to affect the white cells or immune response. Evaluation of hypertensives should always include assessment of renal function. Overall, the most frequently occurring adverse reactions associated with CAPOTEN are skin rash and taste alteration; both effects are generally mild, reversible, or self-limited. See INDICATIONS AND USAGE, WARNINGS, and ADVERSE REACTIONS in the brief summary on the adjacent page.

 $<sup>1.\</sup> Croog\ SH,\ Levine\ S,\ Testa\ MA,\ et\ al:\ The\ effects\ of\ antihypertensive\ therapy\ on\ the\ quality\ of\ life.\ N\ Engl\ J\ Med\ 314(26):1657-1664,\ 1986.$ 

<sup>2.</sup> Data on file, University of Connecticut.



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CAODIFICATION (captopril tablets)
DIFFERENCE

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## **CAPOTEN\* TABLETS**

## Captopril Tablets

INDICATIONS: Hypertension—CAPOTEN (captopril) is indicated for the treatment of hypertension. Consideration should be given to the risk of neutropenia/agranulocytosis (see WARNINGS). CAPOTEN may be used as initial therapy for patients with normal renal function, in whom the risk is relatively low. In patients with impaired renal function, particularly those with collagen vascular disease, captopril should be reserved for those who have either developed unacceptable side effects on other drugs, or have failed to respond satisfactorily to drug combinations. CAPOTEN is effective alone and in combination with other antihypertensive agents, especially thiazide-type diuretics.

Heart Failure: CAPOTEN (captopril) is indicated in patients with heart failure who have not responded adequately to or cannot be controlled by conventional diuretic and digitalis therapy. CAPOTEN is to be used with diuretics and digitalis.

**CONTRAINDICATIONS:** CAPOTEN is contraindicated in patients who are hypersensitive to this product.

WARNINGS: Neutropenia/Agranulocytosis — Neutropenia (1000/mm²) with myeloid hypoplasia has resulted from use of captopril. About half of the neutropenic patients developed systemic or oral cavity infections or other features of the syndrome of agranulocytosis. The risk of neutropenia is dependent on the clinical status of the patient:

granulocytosis. The risk of neutropenia is dependent on the clinical status of the patient: In clinical trials in patients with hypertension who have normal renal function (serum creatinine less than 1.6 mg/dL and no collagen vascular disease), neutropenia has been seen in one patient out of over 8,600 exposed. In patients with some degree of renal failure (serum creatinine at least 1.6 mg/dL) but no collagen vascular disease, the risk in clinical trials was about 1 per 500. Doses were relatively high in these patients, particularly in view of their diminished renal function. In patients with collagen vascular diseases (e.g., systemic lupus erythematosus, scleroderma) and impaired renal function, neutropenia occurred in 3.7% of patients in clinical trials. While none of the over 750 patients in formal clinical trials of heart failure developed neutropenia, it has occurred during the subsequent clinical experience. Of reported cases, about half had serum creatinine ≥ 1.6 mg/dL and more than 75% received procainamide. In heart failure, it appears that the same risk factors for neutropenia are present.

failure, it appears that the same risk factors for neutropenia are present.

Neutropenia has appeared usually within 3 months after starting therapy, associated with myeloid hypoplasia and frequently accompanied by erythroid hypoplasia and decreased numbers of megakaryocytes (e.g., hypoplastic bone marrow and pancytopenia); anemia and thrombocytopenia were sometimes seen. Neutrophils generally returned to normal in about 2 weeks after captopril was discontinued, and serious infections were limited to clinically complex patients. About 13% of the cases of neutropenia have ended fatally, but almost all fatalities were in patients with serious illness, having collagen vascular disease, renal failure, heart failure or immunosuppressant therapy, or a combination of the secomplicating factors. Evaluation of the hypertensive or heart failure patient should always include assessment of renal function. If captopril is used in patients with impaired renal function, white blood cell and differential counts should be evaluated prior to starting treatment and at approximately 2-week intervals for about 3 months, then periodically. In patients with collagen vascular disease or who are exposed to other drugs known to affect the white cells or immune response, particularly when there is impaired renal function, captopril should be used only after an assessment of benefit and risk, and then with caution. All patients treated with captopril should be told to report any signs of infection (e.g., sore throat, fever). If infection is suspected, perform white cell counts without delay. Since discontinuation of captopril and other drugs has generally led to prompt return of the white count to normal, upon confirmation of neutropenia (neutrophil count 1000/mm³) withdraw captopril and closely follow the patient's course.

Proteinuria: Total urinary proteins 1 g per day were seen in about 0.7% of patients on

low the patient's course.

Proteinuria: Total urinary proteins—I g per day were seen in about 0.7% of patients on captopril. About 90% of affected patients had evidence of prior renal disease or received high doses (—150 mg/day), or both. The nephrotic syndrome occurred in about one-fifth of proteinuric patients. In most cases, proteinuria subsided or cleared within 6 months whether or not captopril was continued. The BUN and creatinine were seldom altered in proteinuric patients. Since most cases of proteinuria occurred by the 8th month of therapy with captopril, patients with prior renal disease or those receiving captopril at doses—150 mg per day, should have urinary protein estimates (dip-stick on 1st morning urine) before therapy, and periodically thereafter.

Hypotension: Excessive hypotension was rarely seen in hypertensive patients but is a possibility in severely salt/volume-depleted persons such as those treated vigorously with diuretics (see PRECAUTIONS [Drug Interactions)]. In heart failure, where the blood pressure was either normal or low, transient decreases in mean blood pressure 20% were recorded in about half of the patients. This transient hypotension may occur after any of the first several doses and is usually well tolerated, although rarely it has been associated with arrhythmia or conduction defects. A starting dose of 6.25 or 12.5 mg tid may minimize the hypotensive effect. Patients should be followed closely for the first 2 weeks of treatment and whenever the dose of captopril and/or diuretic is increased.

## BECAUSE OF THE POTENTIAL FALL IN BLOOD PRESSURE IN THESE PATIENTS, THERAPY SHOULD BE STARTED UNDER VERY CLOSE MEDICAL SUPERVISION.

MEDICAL SUPERVISION.

PRECAUTIONS: General: Impaired Renal Function — Hypertension — Some hypertensive patients with renal disease, particularly those with severe renal artery stenosis, have developed increases in BUN and serum creatinine. It may be necessary to reduce captopril dosage and/or discontinue diuretic. For some of these patients, normalization of blood pressure and maintenance of adequate renal perfusion may not be possible. Heart Failure — About 20% of patients develop stable elevations of BUN and serum creatinine 20% above normal or baseline upon long-term treatment. Less than 5% of patients, generally with severe preexisting renal disease, required discontinuation due to progressively increasing creatinine. See DOSAGE AND ADMINISTRATION, ADVERSE REACTIONS [Altered Laboratory Findings]. Valvular Stenosis — A theoretical concern, for risk of decreased coronary perfusion, has been noted regarding vasodilator treatment in patients with aortic stenosis due to decreased afterload reduction. Surgery/Anesthesia — If hypotension occurs during surgery or anesthesia, and is considered due to the effects of captopril, it is correctable by volume expansion.

Drug Interactions: Hypotension — Patients on Diuretic Therapy — Precipitous reduction

Drug Interactions: Hypotension – Patients on Diuretic Therapy – Precipitous reduction of blood pressure may occasionally occur within the 1st hour after administration of the initial of captopril dose in patients on diuretics, especially those recently placed on diuretics, and those on severe dietary salt restriction or dialysis. This possibility can be minimized

by either discontinuing the diuretic or increasing the salt intake about 1 week prior to initiation of captopril therapy or by initiating therapy with small doses (6.25 or 12.5 mg). Alternatively, provide medical supervision for at least 1 hour after the initial dose.

Agents Having Vasodilator Activity – In heart failure patients, vasodilators should be administered with caution.

Agents Causing Renin Release - Captopril's effect will be augmented by antihypertensive

Agents Affecting Sympathetic Activity — The sympathetic nervous system may be especially important in supporting blood pressure in patients receiving captopril alone or with diuretics. Beta-adrenergic blocking drugs add some further antihypertensive effect to captopril, but the overall response is less than additive. Therefore, use agents affecting sympathetic activity (e.g., ganglionic blocking agents or adrenergic neuron blocking agents) with caution.

Agents Increasing Serum Potassium – Give potassium-sparing diuretics or potassium supplements only for documented hypokalemia, and then with caution, since they may lead to a significant increase of serum potassium. Use potassium-containing salt substitutes with caution.

Inhibitors of Endogenous Prostaglandin Synthesis – Indomethacin and other nonsteroidal anti-inflammatory agents may reduce the antihypertensive effect of captopril, especially in low renin hypertension.

**Drug/Laboratory Test Interaction:** Captopril may cause a false-positive urine test for acetone

Carcinogenesis, Mutagenesis and Impairment of Fertility: Two-year studies with doses of 50 to 1350 mg/kg/day in mice and rats failed to show any evidence of carcinogenic potential. Studies in rats have revealed no impairment of fertility.

Pregnancy: Category C: There are no adequate and well-controlled studies in pregnant women. Embryocidal effects and craniofacial malformations were observed in rabbits. Therefore, captopril should be used during pregnancy, or for patients likely to become pregnant, only if the potential benefit outweighs the potential risk to the fetus. Captopril crosses the human placenta.

Nursing Mothers: Captopril is secreted in human milk. Exercise caution when administering captopril to a nursing woman, and, in general, nursing should be interrupted.

Pediatric Use: Safety and effectiveness in children have not been established although there is limited experience with use of captopril in children from 2 months to 15 years of age. Dosage, on a weight basis, was comparable to that used in adults. CAPOTEN (captopril) should be used in children only if other measures for controlling blood pressure have not been effective.

ADVERSE REACTIONS: Reported incidences are based on clinical trials involving approximately 7000 patients.

Renal — About 1 of 100 patients developed proteinuria (see WARNINGS). Renal insufficiency, renal failure, polyuria, oliguria, and urinary frequency in 1 to 2 of 1000 patients.

 ${\it Hematologic} - {\it Neutropenia/agranulocytosis} \ has occurred (see {\it WARNINGS}). \ Anemia, thrombocytopenia, and pancytopenia have been reported.$ 

Dermatologic — Rash, (usually maculopapular, rarely urticarial), often with pruritus, and sometimes with fever and eosinophilia, in about 4 to 7 of 100 patients (depending on renal status and dose), usually during the 1st 4 weeks of therapy. Pruritus, without rash, in about 2 of 100 patients. A reversible associated pemphigoid-like lesion, and photosensitivity, have also been reported. Angioedema of the face, mucous membranes of the mouth, or of the extremities in about 1 of 1000 patients — reversible on discontinuance of captopril therapy. One case of laryngeal edema has been reported. Flushing or pallor in 2 to 5 of 1000 patients.

Cardiovascular – Hypotension may occur; see WARNINGS and PRECAUTIONS [Drug Interactions] for discussion of hypotension on initiation of captopril therapy. Tachycardia, chest pain, and palpitations each in about 1 of 100 patients. Angina pectoris, myocardial infarction, Raynaud's syndrome, and congestive heart failure each in 2 to 3 of 1000 patients.

Dysgeusia – Approximately 2 to 4 (depending on renal status and dose) of 100 patients developed a diminution or loss of taste perception; taste impairment is reversible and usually self-limited even with continued drug use (2 to 3 months). Gastric irritation, abdominal pain, nausea, vomiting, diarrhea, anorexia, constipation, aphthous ulcers, peptic ulcer, dizziness, headache, malaise, fatigue, insomnia, dry mouth, dyspnea, cough, alopecia, paresthesias reported in about 0.5 to 2% of patients but did not appear at increased frequency compared to placebo or other treatments used in controlled trials.

creased trequency compared to placebo or other treatments used in controlled trials.

Altered Laboratory Findings: Elevations of liver enzymes in a few patients although no causal relationship has been established. Rarely cholestatic jaundice, and hepatocellular injury with or without secondary cholestasis, have been reported. A transient elevation of BUN and serum creatinine may occur, especially in volume-depleted or renovascular hypertension patients. In instances of rapid reduction of longstanding or severely elevated blood pressure, the glomerular filtration rate may decrease transiently, also resulting in transient rises in serum creatinine and BUN. Small increases in serum potassium concentration frequently occur, especially in patients with renal impairment (see PRECAUTIONS).

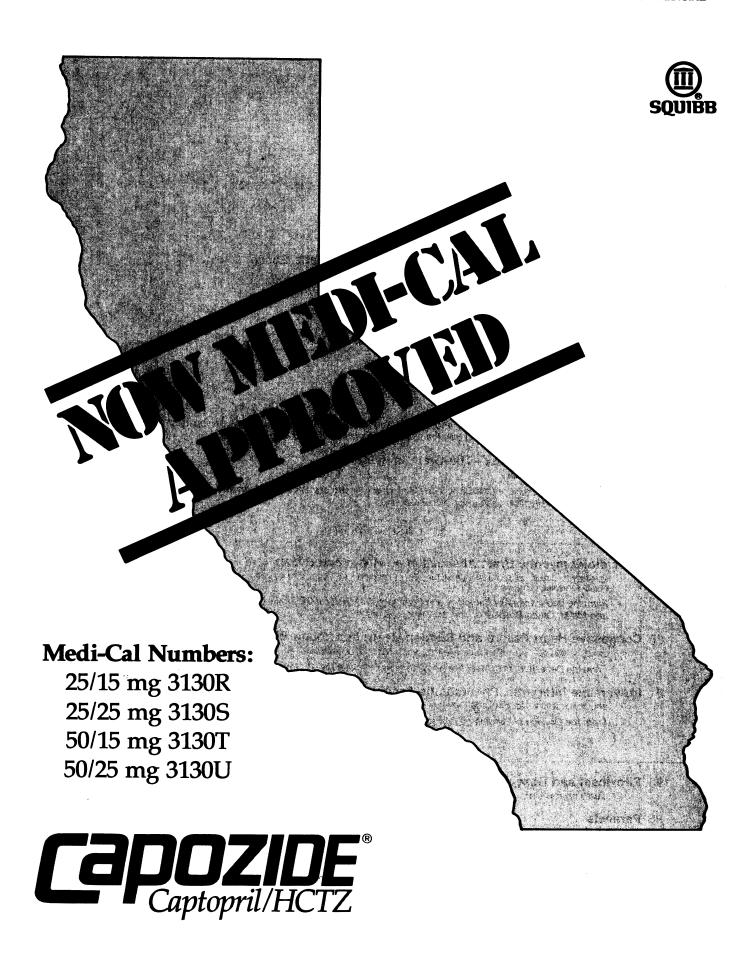
OVERDOSAGE: Primary concern is correction of hypotension. Volume expansion with an I.V. infusion of normal saline is the treatment of choice for restoration of blood pressure. Captopril may be removed from the general circulation by hemodialysis.

DOSAGE AND ADMINISTRATION: CAPOTEN (captopril) should be taken one hour before meals. In hypertension, CAPOTEN may be dosed bid or tid. Dosage must be individualized; see DOSAGE AND ADMINISTRATION section of package insert for detailed information regarding dosage in hypertension and in heart failure. Because CAPOTEN (captopril) is excreted primarily by the kidneys, dosage adjustments are recommended for patients with impaired renal function.

Consult package insert before prescribing CAPOTEN (captopril).

HOW SUPPLIED: Available in tablets of 12.5, 25, 50, and 100 mg in bottles of 100 (25 mg and 50 mg also available in bottles of 1000), and in UNIMATIC unit-dose packs of 100 tablets. (J3-658J)







## ROBERT CHEONG LIM, J.R., M.D.

Professor of Surgery, University of California School of Medicine, San Francisco, California

Chief, Vascular Surgery Service, San Francisco General Hospital Consultant, Letterman Army Medical Center Colonel, U.S. Army Reserve

<u>EDUCATION</u> University of California at Berkeley, A.B.; University of California School of Medicine, San Francisco, M.D.

**RESIDENCY** University of California School of Medicine.

FELLOWSHIPS NIH Fellowship in Vascular Surgery, V.A. Hospital, San Francisco; National Heart Institute Special Fellowship in Thromboembolic Diseases and Microcirculation, University of Gothenburg, Sweden.

OUTSTANDING ACHIEVEMENTS Joe Shoong Fellowship; Earl Hamilton Cornell Scholarship in Medicine; Ligature Order (Sweden); Alpha Omega Alpha; Distinguished Service Award, Youth Opportunity Program, HEW; Special Consultant, Special Project Office on Emergency Medical Services, HEW; Chinese-American Physicians Society; Who's Who in America

My professional career is devoted to patient care, teaching and research. Because of my special interest in the field of trauma surgery, I feel especially close to the work being done at Army medical centers such as Letterman Army Medical Center in San Francisco. I am particularly impressed with what they are doing to prepare young Army surgeons in dealing with trauma injuries.

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Resulting from a lowered heart rate-blood pressure product.5

## Compatible with other antianginals 6+

## Safe in angina with coexisting hypertension, COPD, asthma, or PVD<sup>1,3,5,6</sup>

\*CARDIZEM\* (dilfiozem HCI) is indicated in the treatment of angina pectors due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

'See Warnings and Precautions.

Please see brief summary of prescribing information on the next page.

1419H8





## diltiazem HCI/Marion

## NTIANGINAL PROTECTI **PLUS SAFETY**

Usual maintenance dosage range: 180-360 mg/day

BRIEF SUMMARY Professional Use Information

**CARDIZEM®** 

30 mg, 60 mg, 90 mg and 120 mg Tablets

SUMB, OUNG, 30 mg and 120 mg Tablets

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker. (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, (3 patients with hypotension (less than 90 mm Hg systolic). (4) patients who have demonstrated hypersensitivity to the drug, and (5) patients with acute myocardial infarction and pulmonary congestion documented by x-ray on admission.

WARNINGS

WARNINGS

- VARNINGS

  1. Cardiac Conduction. CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1,243 patients for 0.48%). Concomitant use of dilitazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of dilitazem.

  2. Congestive Heart Failure. Although dilitazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with
- negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (pd/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients. 3. Hypotension. Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
- with CARDIZEM therapy may occasionally result in symptomatic hypotension.

  4. Acute Hepatic Injury. In rare instances, significant elevations in enzymes such as alkaline phosphatase, LDH, SGOT. SGPT. and other phenomena consistent with acute hepatic injury have been noted. These reactions have been reversible upon discontinuation of drug therapy. The relationship to CARDIZEM is uncertain in most cases, but probable in some. (See PRECAUTIONS.)

**PRECAUTIONS** 

PRECAUTIONS
General. CARDIZEM (diltiazem hydrochloride) is extensively
metabolized by the liver and excreted by the kidneys and in
bile. As with any drug given over prolonged periods, laboratory
parameters should be monitored at regular intervals. The drug bile. As with any drug given over prolonge periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of dilitazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes, however, these changes were reversible with continued dosing. Dermatological events (see ADVERS ERACTIONS section) may be transient and may disappear despite continued use of CARDIZEM. However, skin eruptions progressing to erythema multiforme and/or exfoliative dermatitis have also been infrequently reported. Should a dermatologic reaction persist, the drug should be discontinued.

Drug Interaction. Due to the potential for additive effects, caution and careful titration are warranted in patients receiving CARDIZEM concomitantly with any agents known to affect cardiac contractility and/or conduction. (See WARNINGS.)

Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or distable concentration.

Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using bela-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS.) As with all drugs, care should be exercised when treating patients with multiple medications. CARDIZEM undergoes biotransformation by cytochrome P-450 mixed function oxidase.

Coadministration of CARDIZEM with other agents which follow Coadministration of CARDIZEM with other agents which follow the same route of biotransformation may result in the competi-tive inhibition of metabolism. Dosages of similarly metabolized drugs, particularly those of low therapeutic ratio or in patients with renal and/or hepatic impairment, may require adjustment when starting or stopping concomitantly administered CARDIZEM to maintain optimum therapeutic blood levels.

Beta-blockers: Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers controlled is usually well beloched. Available date second.

suggest that concomitant use of CAHDIZEM and beta-are not or digitalis is usually well tolerated. Available data-are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. Administration of CARDIZEM (dilitazem hydrochloride) concomitantly with propranolol in five normal volunteers resulted in increased propranolol levels in all subjects and

resulted in increased propranolol levels in all subjects and bioavailability of propranolol was increased approximately 50%. If combination therapy is initiated or withdrawn in conjunction with propranolol, an adjustment in the propranolol dose may be warranted (See WARNINGS.)

Cimetidine: A study in six healthy volunteers has shown a significant increase in peak diltiazem plasma levels (58%) and area-under-the-curve (53%) after a one-week course of cimetidine at 1,200 mg per day and diltiazem 60 mg per day Ranitidine produced smaller, nonsignificant increases. The effect may be mediated by cimetidine's known inhibition of hepatic cytochrome P450, the enzyme system probably responsible for the first-pass

produced smaller, nonsigniticant increases. The effect may be mediated by cimetidine's known inhibition of hepatic cytochrome P450, the enzyme system probably responsible for the first-pass metabolism of ditliazem Patients currently receiving ditliazem therapy should be carefully monitored for a change in pharmacological effect when initiating and discontinuing therapy with cimetidine. An adjustment in the diffusizem dose may be warranted.

Digitalis: Administration of CARDIZEM with digoxin in 24 healthy male subjects increased plasma digoxin concentrations approximately 20%. Another investigator found no increase in digoxin levels in 12 patients with coronary artery disease. Since there have been conflicting results regarding the effect of digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing CARDIZEM therapy to avoid possible over- or under-digitalization. See WARNINGS.)

Aneathetics: The depression of cardiac contractility, conductivity, and automaticity as well as the vascular dilation associated with anesthetics may be potentiated by calcium channel blockers. When used concomitantly, anesthetics and calcium blockers should be titrated carefully.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A Manothetic strains a sociated a 21 months tuth in misc persent.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

response in in vitro bacterial tests. No intrinsic effect on tertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and tetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stilibirths at doses of 20 times the human dose or greater. There are no well-controlled studies in pregnant women: therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Dilitazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. It use of CARDIZEM is deemed essential, an alternative method of infant feeding should be instituted.

Podistric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded

Cardizem<sup>®</sup> (diltiazem HOl) □ 60 mg
□ 90 mg □ 120 mg Sig: tid

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences as well as their frequency of presentation are: edema (2.4%), headache (2.1%), nausea (1.5%), dizziness (1.5%), rash (1.3%), astheria (1.2%), In addition, the following events were reported infrequently (less than 1%):

Cardiovascular.

d infrequently (less than 1%):
Angina, arrhythmia, AV block (first degree),
AV block (second or third degree—see
conduction warning), bradycardia,
congestive heart failure, flushing,
hypotension, palpitations, syncope,
Amnesia, depression, gait abnormality,
hallucinations, insomnia, nervousness,
oargeethesis, oergonality, beaucusness,

Nervous System. Gastrointestinal:

paresthesia, personality change, somnolence, tinnitus, tremor. Anorexia, constipation, diarrhea dysgeusia, dyspepsia, mild elevations of alkaline phosphatase. SGOT. SGPT, and LDH (see hepatic warnings), vomiting.

Dermatologic.

weight increase. Petechiae, pruritus, photosensitivity, urticaria.

Other:

Amblyopia, CPK elevation, dyspnea, epistaxis, eye irritation, hyperglycemia, nasal congestion, nocturia, osteoarticular pain, polyuria, sexual difficulties.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: alopecia, gingival hyperplasia, erythema multiforme, and leukopenia. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

Issued 3/1/88

See complete Professional Use Information before prescribina

References: 1. Schroeder JS: Mod Med 1982;50(Sept):94-116. 2. Cohn PF, Braunwald E: Chronic ischemic heart disease, in Braunwald E (ed): Heart Disease: A Textbook of Cardiovascular Medicine, ed 2. Philodelphia, WB Saunders Co, 1984, chap 39. 3. O Rourke RA: Am J Cardiol 1985;56:34H-40H. 4. McCall D, Walsh RA, Frohlich ED, ot al. Cur. Pobb Cardiol 1095;10(2): 89.8.5 Existence MH. et al: Curr Probl Cardiol 1985; 10(8):6-80. **5.** Frishman WH, Charlap S. Goldberger J. et al: Am J Cardiol 1985; 56:41H-46H. **6.** Shapiro W: <u>Consultant</u> 1984;24(Dec): 150-159. 7. O'Hora MJ, Khurmi NS, Bowles MJ, et al: Am J Cardiol 1984;54:477-481. 8. Strauss WE, McIntyre KM, Parisi AF, et al: Am J Cardiol 1982; 49:560-566. 9. Feldman RL, Pepine CJ, Whittle J, et al: Am J Cardiol 1982;49:554-559.

Another patient benefit product from PHARMACEUTICAL DIVISION MARION LABORATORIES, INC. KANSAS CITY, MO 64137

Her anxiolytic is working—but she's alert, functioning, and at no risk of a benzodiazepine withdrawal syndrome when therapy ends.



## BuSpar relieves anxiety and returns your patient to normal activity

- ...with no more sedation than induced by placebo
- ...without impairing psychomotor function in most patients\*2
- ...without producing a benzodiazepine withdrawal syndrome<sup>3</sup> upon discontinuation

The first choice for chronic anxiety

## Buspirone HCl) for a different kind of calm

\*Because the effects of BuSpar in any individual patient may not be predictable, patients should be cautioned about operating an automobile or using complex machinery until they are reasonably certain that BuSpar treatment does not affect them adversely.

For Brief Summary, please see following page.

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MJL8-4225



gastroesophy Heartagonist reflux disease

## REFLUX ERUPTS

Zantac dramatically lessens pain of acid reflux¹ by inhibiting the formation of acid at its source—an action unique among pharmaceutical agents indicated for the treatment of gastroesophageal reflux disease.

TATES Tablets

ranitidine HCI/Glaxo

150 mg tablets bid

 Sontag S, Robinson M, McCallum RW, et al: Ranitidine therapy for gastroesophageal reflux disease. Results of a large double-blind trial. Arch Intern Med 1987;147:1485-1491.

Please see next page for Brief Summary of Prescribing Information.

Glaxo/ ROCHE

ZANTAC® 150 Tablets

RRIFF SUMMARY

ZANTAC® 300 Tablets

The following is a brief summary only. Before prescribing, see complete prescribing information in ZANTAC® product labeling.
INDICATIONS AND USAGE: ZANTAC® is indicated in:

- I Short-term treatment of active duodenal ulcer. Most patients heal within four weeks.

  2. Maintenance therapy for duodenal ulcer patients at reduced dosage after healing of acute ulcers.

  3. The treatment of pathological hypersecretory conditions (eg., Zollinger-Ellison syndrome and systemic

mastocytosis).

4. Short-term treatment of active, benign gastric ulcer. Most patients heal within six weeks and the usefulness of further treatment has not been demonstrated.

5. Treatment of gastroesophageal reflux disease (GERD). Symptomatic relief commonly occurs within one or two weeks after starting therapy. Therapy for longer than six weeks has not been studied. In active duodenal ulcer; active, benign gastric ulcer; hypersecretory states; and GERD, concomitant antacids should be given as needed for relief of pain.

CONTRAINDICATIONS: CANTAC® is contraindicated for patients known to have hypersensitivity to the drug. PRECAUTIONS: General: 1. Symptomatic response to ZANTAC® therapy does not preclude the presence of gastric maintains.

of gastric malignancy.

2. Since ZANTAC is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function (see DOSAGE AND ADMINISTRATION). Caution should be observed in patients with hepati

of gastric malignancy.

2. Since ZANTAC is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function (see DOSAGE AND ADMINISTRATION). Caution should be observed in patients with hepatic dysfunction since ZANTAC is metabolized in the liver.

Laboratory Tests: False-positive tests for urine protein with Multistix® may occur during ZANTAC therapy, and therefore testing with sulfosalicylic acid is recommended.

Drug Interactions: Although ZANTAC has been reported to bind weakly to cytochrome P-450 in vitro, recommended doses of the drug do not inhibit the action of the cytochrome P-450-linked oxygenase enzymes in the liver. However, there have been isolated reports of drug interactions that suggest that ZANTAC may affect the bioavailability of certain drugs by some mechanism as yet unidentified (eg. a pht-dependent effect on absorption or a change in volume of distribution).

Carclinogenests, Mutagenests, Impalment of Fertility: There was no indication of tumorigenic or carcinogenic effects in lifespan studies in mice and rats at doses up to 2,000 mg/kg/day.

Rantidine was not mutagenic in standard bacterial tests (Salmonella, Escherichia coli) for mutagenicity at concentrations up to the maximum recommended for these assays.

In a dominant lethal assay, a single oral dose of 1,000 mg/kg to male rats was without effect on the outcome of two matings per week for the next nine weeks.

Pregnancy: Taratogenic Effects: Pregnancy Category B: Reproduction studies have been performed in rats and rabits at doses up to 160 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to ZANTAC. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needd.

Nursing Mothers: ZANTAC is secreted in human milk. Caution should be exercised when ZANTAC is administered to a nursing mother.

Pedi hepatocanalicular or mixed, with or without jaundice.

Musculoskeletal: Rare reports of arthralgias.

Hematologie: Reversible blood count changes (leukopenia, granulocytopenia, thrombocytopenia) have occurred in a few patients. Rare cases of agranulocytosis or of pancytopenia, sometimes with marrow

occurred in a few patients. Hare cases of agranulocytosis of of pancytopenia, sometimes with marrow hypoplasia, have been reported.

Endocrine: Controlled studies in animals and man have shown no stimulation of any pituitary hormone by ZANTAC and no antiandrogenic activity, and cimetidine-induced gynecomastia and impotence in hypersecretory patients have resolved when ZANTAC has been substituted. However, occasional cases of gynecomastia, impotence, and loss of libido have been reported in male patients receiving ZANTAC, but the incidence did not differ from that in the general population.

Integumentary: Rash, including rare cases suggestive of mild erythema multiforme, and, rarely, alopecia.

Other: Rare cases of hypersensitivity reactions (eg, bronchospasm, fever, rash, eosinophilia) and small integrated in severy caracteria.

increases in serum creatinine.

OVERDOSAGE: Information concerning possible overdosage and its treatment appears in the full prescrib-

OVERNOUSAGE: Imministro Concerning possione overdousage and its treatment appears in the full prescribing information.

DOSAGE AND ADMINISTRATION: Active Duodenal Ulcer: The current recommended adult oral dosage is

100 mg twice daily. An alternate dosage of 300 mg once daily at bedtime can be used for patients in whom
dosing convenience is important. The advantages of one treatment regimen compared to the other in a
particular patient population have yet to be demonstrated.

particular patient population have yet to be demonstrated.

Maintenance Therapy: The current recommended adult oral dosage is 150 mg at bedtime.

Pathological Hypersecretory Conditions (such as Zeillinger-Eillson syndrome): The current recommended adult oral dosage is 150 mg twice a day. In some patients it may be necessary to administer ZANTACe 150-mg doses more frequently. Doses should be adjusted to individual patient needs, and should continue as long as clinically indicated. Doses up to 6 g/day have been employed in patients with

Severe disease.

Bealige Gastric Ulser: The current recommended adult oral dosage is 150 mg twice a day.

GERD: The current recommended adult oral dosage is 150 mg twice a day.

GERD: The current recommended adult oral dosage is 150 mg twice a day.

Desage Adjustment for Patients with Imagined Renal Function: On the basis of experience with a group of subjects with severely impaired renal function treated with ZANTAC, the recommended dosage in patients with a creatinine clearance less than 50 ml/min is 150 mg every 24 hours. Should the patient's condition require, the frequency of dosing may be increased to every 12 hours or even further with caution. Hemodialysis reduces the level of circulating rantitidine, Ideally, the dosage schedule should be adjusted so that the timing of a scheduled dose coincides with the end of hemodialysis.

HOW SUPPLIED: ZANTAC® 300 Tablets (rantitidine hydrochloride equivalent to 300 mg of rantitidine) are yellow, capsule-shaped tablets embossed with "ZANTAC 300" on one side and "Glaxo" on the other. They are available in bottles of 30 tablets (NDC 0173-0393-47).

ZANTAC® 150 Tablets (rantitidine hydrochloride activident of the control of the patients) and the control of th

0173-0393-47).

ZANTAC® 150 Tablets (rantitidine hydrochloride equivalent to 150 mg of rantitidine) are white tablets embossed with "ZANTAC 150" on one side and "Glaxo" on the other. They are available in bottles of 60 tablets (NDC 0173-0344-42) and unit dose packs of 100 tablets (NDC 0173-0344-42).

Store between 15" and 30°C (59° and 86°F) in a dry place. Protect from light. Replace cap securely after each opening.

Glaxo

Glaxo Inc. Research Triangle Park, NC 27709

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ZAN516 Printed in USA June 1988

## ANNOUNCING 2nd Annual National AIDS Conference

San Francisco Department of Public Health, and Community Co-sponsors present

## "AIDS: Health Department Leadership and Community Response" September 29, 30 & October 1, 1988 San Francisco

Conference is designed to help local health departments, community leaders, and funders organize a comprehensive community-wide response to the AIDS epidemic.

## **Program Focus**

Partnerships with community agencies Management of the epidemic by local health departments Integration of community resources Substance Abuse Issues AIDS Education in the community Long-term care issues

## **Highlights**

Nationally Renowned Speakers Community Models From Across The U.S. "How To" Workshops Roundtable Discussions

Conference participants: State and local public health administrators; health program managers, educators and planners; healthcare and hospital administrators; mental health and substance abuse program managers; providers of AIDS care (including physicians, nurses and home care); community-based organizers; public officials and staff.

Conference fees: \$125 (before August 1) **\$175** (after August 1) Community-based, non-profit agency official staff: \$50 Persons with AIDS/ARC-Complimentary CE Credit-\$50 additional

Conference registration contact:

## **1988 National AIDS Conference**

c/o Krebs Convention Management Services 555 De Haro, Suite 200 San Francisco, CA 94107 Phone: (415) 255-1297



## The World's Most Popular K\*

potassium chloride slow-release tablets 8 mEq (600 mg)

It means "dependability" in almost any language

\*Based on worldwide sales data on file, CIBA Pharmaceutical Company. Capsule or tablet slow-release potassium chloride preparations should be reserved for patients who cannot tolerate, refuse to take, or have compliance problems with liquid or effervescent potassium preparations because of reports of intestinal and gastric ulceration and bleeding with slow-release KCI preparations.

Before prescribing, please consult Brief Prescribing Information on next page.

## The World's **Most Popular K**

## For good reasons

☐ **It works**—a 12-year record of efficacy¹ ☐ **It's safe**—unsurpassed by any other KCl tablet or capsule<sup>2\*</sup> ☐ It's acceptable vs liquids—greater palatability, fewer GI complaints, lower incidence of nausea2 ☐ It's comparable to 10 mEq—in low-dosage supplementation<sup>3†</sup> ☐ **It's economical**—less expensive than all other leading KCl slow-release supplements on a per tablet cost to the patient 1



Slow-K potassium chloride :slow-release tablets 8mEq(600mg)

For patients who can't or won't tolerate liquid KCI.

\*The most common adverse reactions to potassium salts are gastrointestinal side effects.

†Pooled mean serum potassium following oral administration of 30 mEq K-Tab compared to 24 mEq Slow-K in diuretic-treated hypertensives (n = 20) over 8 weeks.

## CIBA

References: 1. Data on file, CIBA Pharmaceutical Company. 2. Skoutakis VA, Acchiardo SR, Wojciechowski NJ, et al: Liquid and solid potassium chloride: Bioavailability and safety. Pharmacotherapy 1980, 4(6):392-397.

3. Skoutakis VA, Carfer CA, Acchiardo SR: Therapeutic assessment of Slow-K and K-Tab potassium chloride formulations in hypertensive patients treated with thiazide diuretics. Drug Intell Clin Pharm 1987;21:436-440.

Slow-K° potassium chloride USP Slow-Release Tablets 8 mEq (600 mg)

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION SEE PACKAGE INSERT)

INDICATIONS AND USAGE
BECAUSE OF REPORTS OF INTESTINAL AND GASTRIC ULCERATION AND
BLEEDING WITH SLOW-RELEASE POTASSIUM CHLORIDE PREPARATIONS, THESE DRUGS SHOULD BE RESERVED FOR THOSE PATIENTS
WHO CAMNOT TOLERATE OR REFUSE TO TAKE LIQUID OR EFFERVESCENT POTASSIUM PREPARATIONS OR FOR PATIENTS IN WHOM THERE
IS A PROBLEM OF COMPLANCE WITH THESE PREPARATIONS.

1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis; in digitalis intoxication and in patients with hypokalemic
familial periodic paralysis.

2. For prevention of potassium depletion when the dietary intake of potassium is inadequate in the following conditions: patients receiving digitalis
and diuretics for congestive heart failure: hepatic cirrhosis with ascites;
states of aldosterone excess with normal renal function; potassium-losing
nephropathy; and certain diarrheal states.

3. The use of potassium stals in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have
a normal dietary pattern. Serum potassium should be checked periodically,
however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more
severe cases supplementation with potassium salts may be indicated.

CONTRAINDICATIONS

Potassium supplements are contraindicated in patients with hyperkalemia,
since a lurther increase in extram potassium concentration in such patients

severe cases supplementation with potassium salts may be indicated. CONTRAINIDICATONS

Potassium supplements are contraindicated in patients with hyperkalemia, since a further increase in serum potassium concentration in such patients and produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene) (see OVERDOSAGE).

All solid dosage forms of potassium supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementations should be with a liquid preparation. Wax-matrix potassium chlonide preparations have produced esophageal ulceration in certain cardiac patients with esophageal compression due to an enlarged left atrium. WARNINGS

Hyperkalemia (See OVERDOSAGE). In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium onally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic.

The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction With Potassium-Sparing Diuretics
Hypokalemia should not be treated by the concomitant administration of
potassium sats and a potassium-sparing diuretic (e.g., spironolactone or
triamterene), since the simultaneous administration of these agents can
produce severe hyperkalemia.

Gastrointestinal Lesions

produce severe hyperkalemia. Bastinitestinal Lesions Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel tablets have produced stenotic and/or ulcerative lesions of the small bowel tablets have produced stenotic and yo high localized concentration of potassium ion in the region of a rapidly dissolving tablet, which injures the bowel wall and thereby produces obstruction, hemorhage, or perforation. Slow-K is a wax-matrix tablet formulated to provide a controlled rate of release of potassium chloride and thus to minimize the possibility of a high local concentration of potassium on near the bowel wall. While the reported frequency of small-bowel lesions is much less with exar-matrix tablets (less than one per 100,000 patient-years) tann with enteric-coated potassium chloride tablets (40-50 per 100,000 patient-years) case associated with wax-matrix tablets have been reported both in foreign countries and in the United States. In addition, perhaps because the wax-matrix preparations are not enteric-coated and release potassium in the stomach, there have been reports of upper gastrointestinal bleeding associated with these products. The total number of gastrointestinal lesions remains approximately one per 100,000 patient-years. Slow-K should be discontinued immediately and the possibility of bowel obstruction or perforation considered if severe vormiting, abdominal pain, distention, or gastrointestinal bleeding occurs. Metabolic Acidosis
Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, or potassium acetate.

trate, or potassium acetate. **PRECAUTIONS** 

General:

The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physicians should bear in-mind that acute alkialosis per se can produce hypokalemia in the absence of a deficit in total body potassium, while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. Information for Patients

Physicians should consider reminding the patient of the following:

To take each dose without crushing, chewing, or sucking the tablets.

To take this medicine only as directed. This is especially important if the patient is also taking both divertics and digitalis preparations.

To check with the physician if there is trouble swallowing tablets or if the tablets seem to stick in the throat.

To check with the doctor at once if tarry stools or other evidence of gastrointestinal bleeding is noticed.

pastrointestrial breening is noticed. Laboratory Test Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Potassium-sparing diuretics: see WARNINGS.

Drug Interactions
Potassium-spaning diuretics: see WARNINGS.
Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term carcinogencity studies in animals have not been performed.
Pregnancy Category C
Animal reproduction studies have not been conducted with Slow-K. It is also not known whether Slow-K can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Slow-K should be given to a pregnant woman only if clearly needed.

Nursing Mothers

The normal patassium jon content of human milk is about 13 mEn/L. It is not

The normal potassium ion content of human milk is about 13 mEq/L. It is not known if Slow-K has an effect on this content. Caution should be exercised when Slow-K is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

regiaric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
One of the most severe adverse effects is hyperkalemia (see CONTRAINDICATIONS, WARNINGS, and OVERDOSAGE). There also have been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see CONTRAINDICATIONS and WARNINGS); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose.

Skin rash has been reported rarely.

OVEROOSAGE
The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes senous hyperkalemia. However, if excretory mechanisms is empaired or if potassium is administered too rapidly intravenously, potentially tatal hyperkalemia can result (see CONTAINIONS) and WARNINGS). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration (5-8.0 mEq.L) and characteristic electrocardiographic changes (peaking of T waves, loss of P wave, depression of S-T segment, and prolongation of the C1 interval). Ireatment measures for hyperkalemia include the following: (1) elimination of foods and medications containing potassium and of potassium-paring diuretics; (2) intravenous administration of 300-500 ml/hr of 10% dextrose solution containing in patients who have been stabilized on digitalis, toor rapid a lowering of the serum potassium by the averane adult is 40.80 mEg. exc.

Description of the patient of the proper and the proper and the proper and produce digitalis toxicity.

DOSAGE AND ADMINISTRATION

digitalis toxicity.

DOSAGE AND ADMINISTRATION

digitalis toxicity.

DOSAGE AND ADMINISTRATION

The usual dietary intake of potassium by the average adult is 40-80 mEq per day. Potassium depletion sufficient to cause hypokalemia usually requires the loss of 200 or more mEq of potassium from the total body store. Dosage must be adjusted to the individual needs of each patient but is typically into the range of 20 mEq per day for the prevention of hypokalemia to 40-100 mEq or more per day for the treatment of potassium depletion. Large numbers of tablets should be given in divided doses.

Note: Slow-K slow-release tablets must be swallowed whole and never crushed, chewd, or sucked.

HOW SUPP-LIED

Tablets – 600 mg of potassium chloride (equivalent to 8 mEq) round, buff colored, sugar-coated (imprinted Slow-K)

Bottles of 1000 NDC 0083-0165-30

Bottles of 1000 NDC 0083-0165-30

Consumer Pack — One Unit

12 Bottles — 100 tablets each NDC 0083-0165-65

Accu-Pake Unit Dose (Bilster pack)

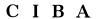
Box of 100 (strips of 10) NDC 0083-0165-32

Do not store above 86°F (30°C). Protect from moisture. Protect from light.

Dispense in tight, light-resistant container (USP).

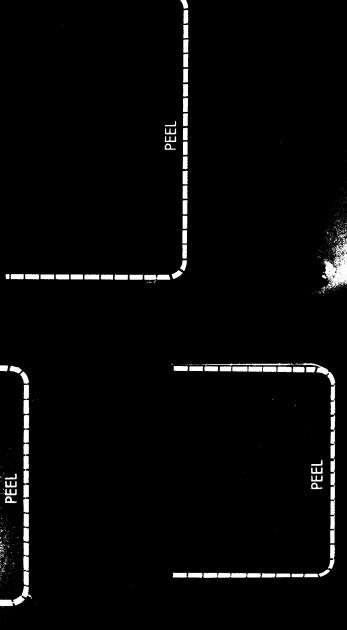
Dist. by: CIBA Pharmaceutical Company Division of CIBA-GEIGY Corporation Summit, New Jersey 07901

C87-31 (Rev. 8/87)



128-3568-A

## INSIDE STORY IN HYPERTENSION



## TRANDATE bid

labetalol HCl/Glaxo 100 mg tablets Because it vasodilates

idence of Limpolance<sup>7</sup> es exercise

sloothoressure control

HCI/Glaxe 10 and tablets e it vas a dilcates

References: 1. Malini PL, Strocchi E, Negroni S, et al: Renal haemodynamics after chronic treatment with labetalol and propranolol. Br J Clin Pharmacol 1982;13(suppl 1):1235-1265. 2. Pedersen EB, Larsen JS: Effect of propranolol and labetalol on renal haemodynamics at rest and during exercise in essential hypertension. Postgrad Med J 1980;56(suppl 2):27-32. 3. Wallin JD: Antihypertensives and their impact on renal function. Am J Med 1983;75:103-108. 4. Koch G: Haemodynamic adaptation at rest and during exercise to long-term antihypertensive treatment with combined alpha- and beta-adrenoreceptor blockade by labetalol. Br Heart J 1979;41(2):192-198. 5. Feit A, Holtzman R, Cohen M, agrenoreceptor nockage by labetalon. Br Heart J 1973;41(2):192-196. B. Fett A, notzman H, Conen H et al: Effect of labetalol on exercise tolerance and double product in mild to moderate essential hypertension. Am J Med 1985;78:937-941. 6. Lund-Johansen P: Short- and long-term (six-year) hemodynamic effects of labetalol in essential hypertension. Am J Med 1983;75:24-31. 7. Burris JF, Goldstein J, Zager PG, et al: Comparative tolerability of labetalol versus propranolol, atenolol, pindolol, metoprolol, and nadolol. J Clin Hypertens 1986;3:285-293.

## TRANDATE® Tablets (labetaloi hydrochloride)

BRIEF SUMMARY

The following is a brief summary only. Before prescribing, see complete prescribing information in TRAMDATE® Tablets product labeling.

CONTRAINDICATIONS: TRANDATE® Tablets are contraindicated in bronchial asthma, overt cardiac

failure, greater-than-first-degree heart block, cardiogenic shock, and severe bradycardia (see WARN-

WARNINGS: Cardiac Failure: Sympathetic stimulation is a vital component supporting circulatory function in congestive heart failure. Beta-blockade carries a potential hazard of further depressing invocation in Congestive fleat is unlike. Seta-vocate carries a potential intact of intriure depressing impocardial contractility and precipitating more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, labetalol HCl can be used with caution in patients with a history of heart failure who are well compensated. Congestive heart failure has been observed in patients receiving labetalol HCl. Labetalol HCl does not abolish the inotropic action of digitalis on heart muscle.

la Patients Without a History of Cardiac Failure: In patients with latent cardiac insufficiency, contin-ued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, patients should be fully digitalized and/or be given a diuretic, and the response should be observed closely. If

should be fully digitalized and/or be given a diuretic, and the response should be observed closely. If cardiac failure continues despite adequate digitalization and diuretic, TRANDATE® therapy should be withdrawn (gradually, if possible).

Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal: Angina pectoris has not been reported upon labetalol HCI discontinuation. However, hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy, exacerbation of angina and, in some cases, myocardial infarction have occurred after abrupt discontinuation of such therapy. When discontinuing chronically administered TRANDATE, particularly in patients with ischemic heart disease, the dosage should be gradually reduced over a period of one to two weeks and the patient should be carefully monitored. If angina markedly worsens or acute coronary insufficiency develops, TRANDATE administration should be reinstituted promptly, at least temporarily, and other measures appropriate for the management of unstable angina should be taken. Patients should be warned against interruption or discontinuation of therapy without the physician's advice. Because coronary artery disease is common and may be unrecognized, if may be prudent not to discontinue TRANDATE therapy abruptity even in patients treated only for hypertension.

\*\*Menallergie Bronchespasm\*\* (eg. Chronic Bronchitts and Emphysema): Patients with bronchospastic disease should, in general, not receive beta-blockers. TRANDATE may be used with caution, however, in patients who do not respond to, or cannot tolerate, other antihypertensive agents. It is prudent, if TRANDATE is used, to use the smallest effective dose, so that inhibition of endogenous or exogenous beta-agonists is minimized.

exogenous beta-agonists is minimized.

Pheochromocytoma: Labetalol HCl has been shown to be effective in lowering blood pressure and

Phoechromocytoma: Labetalol HCl has been shown to be effective in lowering blood pressure and relieving symptoms in patients with pheochromocytoma. However, paradoxical hypertensive responses have been reported in a few patients with this tumor; therefore, use caution when administering labetalol HCl to patients with pheochromocytoma.

Diabetas Mellitus and Hypeglycemia: Beta-adrenergic blockade may prevent the appearance of premonitory signs and symptoms (eg. tachycardia) of acute hypoglycemia. This is especially important with labile diabetics. Beta-blockade also reduces the release of insulin in response to hyperglycemia; it may therefore be necessary to adjust the dose of antidiabetic drugs.

Major Sargery: The necessity or desirability of withdrawing beta-blocking therapy before major surgery is controversial. Protracted severe hypotension and difficulty in restarting or maintaining a heartbeat have been reported with beta-blockers. The effect of labetalol HCl's alpha-adrenergic activity has not been evaluated in this setting. near used there been reported with beta-blockers. The effect of nabetallor from a applia-authenique activit has not been evaluated in this setting.

A synergism between labetalol HCl and halothane anesthesia has been shown (see PRECAUTIONS:

Drug Interactions).

PRECAUTIONS: General: Impaired Hepatic Function: TRANDATE® Tablets should be used with caution

In patients with impaired hepatic function since metabolism of the drug may be diminished.

Jaundice or Hepatic Dysfunction: On rare occasions, labetalol HCl has been associated with jaundice (both hepatic and cholestatic). It is therefore recommended that treatment with labetalol HCl be stopped immediately should a patient develop jaundice or laboratory evidence of liver injury. Both

have been shown to be reversible on stopping therapy.

Information for Patients: As with all drugs with beta-blocking activity, certain advice to patients being treated with labetalol HCI is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects. While no incidence of the abrupt withdrawal phenomenon (exacerbation of angina pectoris) has been reported with labetalol HCI, dosing with TRANDATE Tablets should not be interrupted or discontinued without a physician's advice. Patients being treated with TRANDATE Tablets should consult a physician at any sign of impending cardiac failure. Also, transient scalp tingling may occur, usually when treatment with TRANDATE Tablets is initiated (see ADVERSE REACTIONS).

Laboratory Tests: As with any new drug given over prolonged periods, laboratory parameters should be observed over regular intervals. In patients with concomitant illnesses, such as impaired renal

function, appropriate tests should be done to monitor these conditions.

Drug Interactions: In one survey, 2.3% of patients taking labetalol HCl in combination with tricyclic antidepressants experienced tremor as compared to 0.7% reported to occur with labetalol HCl alone. The contribution of each of the treatments to this adverse reaction is unknown, but the possibility of a drug interaction cannot be excluded.

Drugs possessing beta-blocking properties can blunt the bronchodilator effect of beta-receptor agonist drugs in patients with bronchospasm; therefore, doses greater than the normal antiasthmatic

agonist drugs in patients with pronchiospasm; therefore, doses greater than the normal anuasumal dose of beta-agonist bronchodilator drugs may be required.

Cimetidine has been shown to increase the bioavailability of labetalol HCl. Since this could be explained either by enhanced absorption or by an alteration of hepatic metabolism of labetalol HCl, special care should be used in establishing the dose required for blood pressure control in such

Synergism has been shown between halothane anesthesia and intravenously administered labetalol HCI. During controlled hypotensive anesthesia using labetalol HCI in association with halothane, high concentrations (3% or above) of halothane should not be used because the degree of hypotension will

## TRANDATE® Tablets (labetalol hydrochloride)

be increased and because of the possibility of a large reduction in cardiac output and an increase in central venous pressure. The anesthesiologist should be informed when a patient is receiving labetalol

Labetalol HCl blunts the reflex tachycardia produced by nitroglycerin without preventing its hypo-tensive effect. If labetalol HCl is used with nitroglycerin in patients with angina pectoris, additional antihypertensive effects may occur.

Drug/Laboratory Test Interactions: The presence of a metabolite of labetalol in the urine may result in falsely increased levels of urinary catecholamines when measured by a nonspecific trihydroxyindole (THI) reaction. In screening patients suspected of having a pheochromocytoma and being treated w labetalol HCI, specific radioenzymatic or high performance liquid chromatography assay techniques should be used to determine levels of catecholamines or their metabolites.

should be used to determine levels of catecholamines or their metabolites.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term oral dosing studies with labetalol HCl for 18 months in mice and for two years in rats showed no evidence of carcinogenesis. Studies with labetalol HCl using dominant lethal assays in rats and mice and exposing microorganisms according to modified Ames tests showed no evidence of mutagenesis.

Preguancy: Teratogenic Effects: Pregnancy Category C: Teratogenic studies were performed with labetalol in rats and rabbits at oral doses up to approximately six and four times the maximum recommended human dose (MRHD), respectively. No reproducible evidence of fetal malformations was observed. Increased fetal resorptions were seen in both species at doses approximating the MRHD. A teratology study performed with labetalol in rabbits at intravenous doses up to 1.7 times the MRHD. revealed no evidence of drug-related harm to the fetus. There are no adequate and well-controlled studies in pregnant women. Labetalol should be used during pregnancy only if the potential benefit

justifies the potential risk to the fetus.

Nonteratogenic Effects: Infants of mothers who were treated with labetalol HCl during pregnancy did not appear to be adversely affected by the drug. Oral administration of labetalol to rats during late gestation through weaning at doses of two to four times the MRHD caused a decrease in neonatal

Labor and Delivery: Labetalol HCl given to pregnant women with hypertension did not appear to affect the usual course of labor and delivery.

Mursing Mothers: Small amounts of labetalol (approximately 0.004% of the maternal dose) are excreted in human milk. Caution should be exercised when TRANDATE Tablets are administered to a

nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Most adverse effects are mild, transient, and occur early in the course of ADVERSE REACTIONS: Most adverse effects are mild, transient, and occur early in the course of TRAND. TRANSPACE CAPTURES. MUST adverse effects are finely, datasetin, and occur early in the course of treatment. In controlled clinical trials of three to four months' duration, discontinuation of TRANDATE\*

Tablets due to one or more adverse effects was required in 7% of all patients. In these same trials, beta-blocker control agents led to discontinuation in 8% to 10% of patients, and a centrally acting alpha-agonist in 30% of patients.

The following adverse reactions were derived from multicenter, controlled clinical trials over treatment periods of three and four months. The rates, which ranged from less than 1% to 5% except as otherwise noted, are based on adverse reactions considered probably drug-related by the investigator. If all reports are considered, the rates are somewhat higher (eg, dizziness, 20%; nausea, 14%; fatigue, 11%). **Body as a Whole:** Fatigue, asthenia, headache. **Gastrointestinal:** Nausea (6%), vomiting, dyspep-

so y as a whole: ratigue, asthenia, neadache. Gastrointestinat: Aussea (6%), vomitting, dyspensia, diarrhea, taste distortion. Central and Peripheral Nervous Systems: Dizziness (11%), paresthesia, drowsiness. Autonomic Nervous System: Nasal stuffiness, ejaculation failure, impotence, increased sweating. Cardiovascular: Edema, postural hypotension. Respiratory: Dyspnea. Skin: Rash. Special Senses: Vision abnormality, vertigo.

The adverse effects were reported spontaneously and are representative of the incidence of adverse effects that may be observed in a properly selected hypertensive patient population, ie, a group excluding patients with bronchospastic disease, overt congestive heart failure, or other contraindications to help-blocket these.

containing patients with utinicipatatic disease, over congestive near failure, or other contraindica-tions to beta-blocker therapy.

Clinical trials also included studies utilizing daily doses up to 2,400 mg in more severely hyperten-sive patients. The US therapeutic trials data base for adverse reactions that are clearly or possibly dose-related shows that the following side effects increased with increasing dose: dizziness, fatigue, nausea, vomiting, dyspepsia, paresthesia, nasal stuffiness, ejaculation failure, impotence, and edema. In addition, a number of other less common adverse events have been reported in clinical trials or

the literature: the interature:

Cardiovascular: Postural hypotension, including, rarely, syncope. Central and Peripheral Nervous

Systems: Paresthesia, most frequently described as scalp tingling. In most cases, it was mild,
transient, and usually occurred at the beginning of treatment. Collagen Disorders: Systemic lupus
erythematosus; positive antinuclear factor (ANF). Eyes: Dry eyes. Immunological System: Antimitochondrial antibodies. Liver and Billary System: Cholestasis with or without jaundice. Musculoskeletal System: Muscle cramps, toxic myopathy. Respiratory System: Bronchospasm. Skin and
Anneadesce. Reshe of the vicious bronches.

Appendages: Rashes of various types, such as generalized maculopapular, lichenoid, urticarial, bullous lichen planus, psoriaform, and facial erythema; Peyronie's disease; reversible alopecia. Urinary System: Difficulty in micturition, including acute urinary bladder retention. Following approval for marketing in the United Kingdom, a monitored release survey involving approximately 6,800 patients was conducted for further safety and efficacy evaluation of this product. Results of this survey indicate that the type, severity, and incidence of adverse effects were comparable to these cited above. to those cited above

to those cited above.

Potential Adverse Effects: In addition, other adverse effects not listed above have been reported with other beta-adrenergic blocking agents. Central Nervous System: Reversible mental depression progressing to catatonia, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on psychometrics. Cardiovascular: Intensification of AV block (see CONTRAINDICATIONS).

Allergic: Fever combined with aching and sore throat; laryngospasm, respiratory distress. Hemato-logic: Agranulocytosis, thrombocytopenic or nonthrombocytopenic purpura. Gestrointestinal:

Mesenteric artery thrombosis, ischemic colitis. The oculomucocutaneous syndrome associated with the beta-blocker practolol has not been reported with labetalol HCI.

Clinical Laboratory Texts: There have been reported with labetalol HCI.

Clinical Laboratory Tests: There have been reversible increases of serum transaminases in 4% of patients treated with labetalol HCl and tested, and more rarely, reversible increases in blood urea.

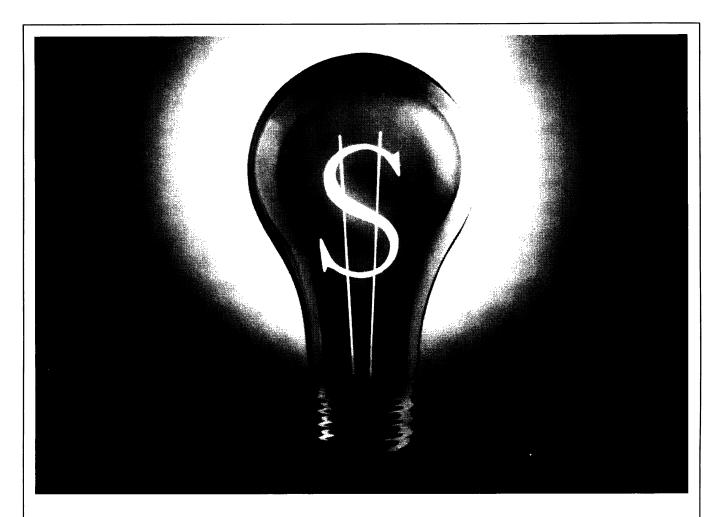
OVERDOSAGE: Information concerning possible overdosage and its treatment appears in the full prescribing information. **DOSAGE AND ADMINISTRATION:** DOSAGE MUST BE INDIVIDUALIZED. The recommended *initial* 

dosage is 100 mg nivice daily whether used alone or added to a diuretic regimen. After two or three days, using standing blood pressure as an indicator, dosage may be titrated in increments of 100 mg bid every two or three days. The usual maintenance dosage of labetalol HCl is between 200 and 400 mg (wice daily. Before use, see complete prescribing information for dosage details.

April 1988

## Glaxo

Glaxo Inc., Research Triangle Park, NC 27709



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CNA's financial stability provides the security you need in an insurer. CNA will be able next year, and in the years after that, to honor the commitments it has made because CNA has the resources to adequately finance your professional liability coverage.

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## The portrait of anxiety

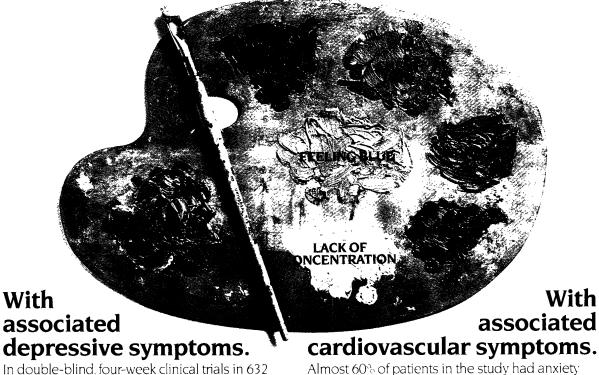


**Upjohn** The Upjohn Company Kalamazoo. Michigan 49001 USA

Please see adjacent page for brief summary of prescribing information.

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## is often complicated



In double-blind, four-week clinical trials in 632 patients with moderate to severe anxiety, therapy with XANAX was compared with placebo.

XANAX was significantly more effective (P<.001) than placebo in relieving the anxiety with over half of the patients showing marked to moderate improvement by the first evaluation period (one week).

In addition over 70% of these patients

experienced associated moderate to severe depressed mood. XANAX was shown to be significantly more effective (*P*<.014) than placebo in improving the associated depressed mood.



Almost 60% of patients in the study had anxiety with associated cardiovascular symptoms even though cardiovascular disease had been ruled out. XANAX was shown to effectively relieve anxiety including the associated cardiovascular symptoms.

XANAX the first of a unique class—the

triazolobenzodiazepines.

■ Well tolerated—Side effects. if they occur are generally observed at the beginning of therapy and usually disappear with continued medication. Drowsiness and light-headedness were the most commonly reported adverse reactions.

most commonly reported adverse reactions.

Sustained efficacy—No reported increase in dosage during 16-week clinical study once an appropriate dosage was achieved. Since long-term effectiveness of XANAX has not been established it is recommended that it not be used for longer than 16 weeks.

■ Simple dosage—0.25 to 0.5 mg t.i.d.



for the relief of complicated anxiety



## Brief Summary, Consult the package insert for prescribing information.

Indications and Usage: Axid, is indicated for up to eight weeks for the freatment of active duodenal uter it missipatients the user will need within four week. Axid is indicated for maniferance therapy for duodenal user patients at a reduced dosage of 150 mg his after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year.

 $\begin{tabular}{ll} \textbf{Contraind cated in patients with known hypersensitivity} to the drug and should be used with caution in patients with hypersensitivity to other H$_2$-receptor antagonists. \\ \end{tabular}$ 

oner in-precipitor antagonists.

Precautions: Genera:—1. Symptomatic response to nizatid ne therapy does not preclude the presence of gastric malignancy.

2. Because nization is secreted or immarily by the kidney, dosage should be reduced in platents with moderate to sever enail insufficiently.

3. Pharmacokinetic studies in patients with nepational syndrome have not been done Part of the dose of matadoners in readolized in the liver in parties with normal renal function and uncomplicated hepatic dysfunction the disposition of matadoners is mitrat to that in pormal subjects.

Laboratory Pists—False-positive tests for unoblinogen with Multistix in majoration the property with matadoners.

disposition of matchine is similar to that in normal subjects. Laboratory 1951s. False-sook the tests for unoblinoger with Multistia\* majoccur during therapy with matchine. Drug Interactions—No interactions—Published drug—netabloring enzyme system interefore drug—netactions—modified by inhibition of hepatic metablorism and not excepted to occur in patients given very high dosses (3,900 mg) of aspirin daily, increases in serium salicylate evers were seen when reading in some properties of the p

compared to concurrent controls, and evidence of mild liver injury, transaminase elevations. The occurrence of a marginal finding at they dose only, in an mais given an excessive and somewhat head took dose, with no evidence of a carcinogenic effect in rats, materimise, and ternale mice, given by the other states are mice, and ternale mice, given by the other states and considered evidence of a carcinogen colenta for AMA. Axid was not mutagenic in abote yot tests performed to evaluate its potential penetic toxicity. Indicate penetral mutation tests unscheduled DMA synthesis steer chromatic exchange and them thouse lymphoma assay. In a two-generation, perinatal and postnatal festivity study in rats, doses of initiation of the property of the

assumed to be secreted in human milk, and caution should be ever sed when intaidness administered to nutrising mothers. Pediatric User—Salety and effectiveness in this first have not been established. User in Elizary Patients—User healing rates in eitem, patients are similar to those in younger age groups. The incidence rates of adverse events and abortatry test abnormalities are also stimilar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Eiderly patients may have reduced renal function.

patients may have reduced renal function. Adverse Reactions: Clinical trias of invalidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic piacebo-controlled it als included over 1,900 patients given invalidine and over 1,000 given bilacebo Among the more common adverse events in the domestic plazebo-controlled trias sweating 11% is 0.02% in unicar and 0.5% is 0.01% and somnoience 12.4% is 0.13% in were sign floatify more common in the nizationer group. A variety of less common events was also reported. It was not possible to Axid\* inizatione Lilly

determine whether these were caused by nizatione importance in the modificial replactice up an injury, exidenced by elevated hiver enzymeitests SGOT AST, SGPT ALT, or alwane processhase, cocurred in some patients pass 5 kilon popular. He also in taking the processors of SGOT SGOT SGOT services in precise than 500 folion, and in a single restance SGOT was greater than 500 folion, and in a single restance SGOT was greater than 500 folion, and in a single restance SGOT was greater than 500 folion, and in a single restance soft was greater than 500 folion. The overal rate of occurrence of exercise and exercises after discontinuation of that.

Cardiovascular—in our inclination and exercises and instead Axid and in three untreaters subjects.

Endocrine—Our call praintancising, studies and control edition call this showed no evidence of anti-androgen data, it, due to Axid impotence and decreased to do were reported with each exercisely by patients with ordered Axid and by mose given patients. Place found that the subject of the patient who was treated with Axid discontinuation.

He mandoog of Fata from noticitized a value of the order of the subject of the discontinuation and the subject of the discontinuation of the subject of the su

Overdosage: There is little or incarexperience with overdosage of Axid in numbers, if overdosage occurs use of activated charical lemests or lawage should be considered along withich had more toning and supportive the

reproducts Stronger to six founds increased beamar evaluate by applical matery. Str. Test an mass that received large doses of invasione have exhibited the intergent type effects including fact mation Service that precess, the song a grand distribution of the song and distrib

Axiat rigatione bis



Eli Lilly and Company Indianapolis, Indiana

## A better alternative for hypertensives who are going bananas...

Spare your patients the extra costin calories, sodium and dollars.

Spare your patients the rigors of dietary K+supplementation.

25mg Hydrochlorothiazide/50mg Triamterene/5KF

Effective antihypertensive\* therapy...without the bananas

> DAW 'DYAZIDE' AS WRITTEN.

\* Not for initial therapy. See brief summary.

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.



## Brief Summary. Consult the package insert for prescribing information.

Indications and Usage Avoil sing cased for up to eight weeks for the treatment of active doodenat user. If most patients the user will hear within four weeks. Avoil is indicated for maintenance therapy for guidarea user but early a reduced dosage of 1.50 mg in such meaning of an active budger at user. The consequences of continuous treapy, with Avoil to ringe that one week.

**Contraindication:** Axides contraindicated in patients with known hypersensit vity to the drug and should be used with caution in patients with hypersensity U to other  $H_2$ -receptor antagonists.

to the drug and should be used with caution in patients withing persensity. It to other Hymecetor antagonists.

Precautions: General — 3 Symptomatic response to nationne therapy open or preduced the presence of gash timalignancy.

2 Because relationes is excreted primary, by the kidney dosage should be reduced in patients with moderate to severe enablins, fitners,

3 Pharmacokinetic studies in patients with hepaticenal syndrome have not been done. Part of the dose of nationes in metabolized in the view in patients with normal renal function and undomn patient by each of the view in patients with normal renal function and undomn patient by the patients of useful of the dose of nationes is metabolized in the view in patients. Caporatory Fasts — False past to that in normal specific dust function the dosostion of invatidine is similar formal in normal specific and surface of Drug Interactions. How the transplant is personal the object of the drug metabolizing enzyme system, therefore drug interactions mediated by unnot be to in color inspatient of any increases in serum salicytist evels where the accompanies of the patients of the pati

compared to concurrent controls, and evidence of mild liver injury, transammase elevations. The occurrence of a marginal finding at high dose only, in an mals given an excessive, and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice igner up to 360 mg kg day, about 60 mes the human dose, and a negative multagench, battery is not considered evidence of a carcinogenic obtential for Axic. Axid was not multagenic to abattery of tests beformed to evaluate its potential genetic toxicity, including pacterial multation tests, unscreeded to MA synthesis sister chromatic extrange, and abutery of tests beformed to evaluate its potential genetic toxicity, including pacterial multation tests, unscreeded to MA synthesis sister chromatic extrange in permatal and postnaral fertify study in rats doses of hazbone up to 650 mg kg day, produced moladress effects on the exproduction studies in rats at doses up to 300 times the human dose and in Dutch Better abotts and doses up to 300 times the human dose and in Dutch Better abotts and doses so to 55 mes the human dose and in Dutch Better abotts and doses at the 35 mesh burban dose created now exceed of margared fertify to iteratogenic effect, but at a dose education to 300 times the human dose and molations. The studies in care and decreased the studies of the studi

assumed to be secretic in human mix, and caution should be execused when nationers administered to mixing mothers. Pedatric use—Safety and effectiveness in children have not been established. Use in Edetry Patients—Uncer healing cases in edemy patients are stimulated those in younger lage groups. The incidence rates of adverse events and aboratory test abnormalities are assisting in otherses seen in other age groups. Age alone may not be an important factor in the disposition of initiating re-patients may have reduced renal function.

patients may have reduced renaflunction. Adverse Reactions: Clinical thials of inzatidine included almost 5,000 patients given inzatidine in studies of varying durations. Domestic placebo-controlled thats included over 1,000 patients given inzatidine and over 1,000 given piacebo Among the more common adverse events in the domestic patiencebo-controlled trials is sweating 1.72 vio 0.25 Livit canal 0.55 vis 1,00 °°20 Livit canal someolence 1,2 4% vis 1,29% were significantly more common in the bizatidine group. A variety of less common events was also reported. If was not possible to Axid 1 inzatidine Litily).

determine whether these were caused by nizatidine impacts—Hepatocellular injury evidenced by elevated liver enzyme tests. SG0T [AST]. SGPT [ALT] or alkaline phosphatase; occurred in some patients possibly or probably related to nizatidine in some cases, there was marked elevation of SG0T SGPT enzymes, greater that S00 IU L. and in a single instance. SGPT was greater than 2000 IU L. The overal rate of occurrences of elevated river enzymes and elevations to three times the upper limit of normal however due nots grint cantilly differ from the rate of liver enzyme abhormalities in piaceto-treated patients. All abnormalities were reversible after discontinuation of land.

of Axid Cardiovascular—In cinical pharmacology studies, short episodes of asymptomatic vertricular tachycardia occurred in two individuals administered Axid and in three untreated subjects. Endocrine—Clinica in pharmacology studies and controlled clinical trials snowed no evidence of antiandrogenic activity due to Axid. Impotence and decreased highor were reported with equal requestly objectives who received Axid and by those given placebo. Pare reports of gynecomastia occurred. Hematologic—Fatal thrombocytopenia was reported in a patient who was treated with Axid and another Hy-receptor antagonist. On previous occasions his patient had experienced thrombocytopen a white faking other drugs. Integumental—Sweating and urticaria were reported significantly more frequently in nizatidine than in piacebo patients. Rash and extorative dermatitis were a screedorted.

Hyperur cemia unassociated with gout or nephrolithiasis was

reported

Overdosage: There is little orinical experience with overdosage of Axid in numars. If overdosage accurs use of activated charcoal lemess or lavage should be considered along with chical monitoring and supportive therapy. Recall dialysis for four to six hours increased plasma clearance by approximately less an mass that received large ocses of initiations where exhibited cholinergic-type effects including lacrimation is a valor meass mosts, and diarrhea. Single oral coses of 800 mg kg in dogs and of 1,200 mg kg in monkeys were not lethal intraverous 25% values in the rat and mouse were 301 mg kg and 232 mg kg in expectively.

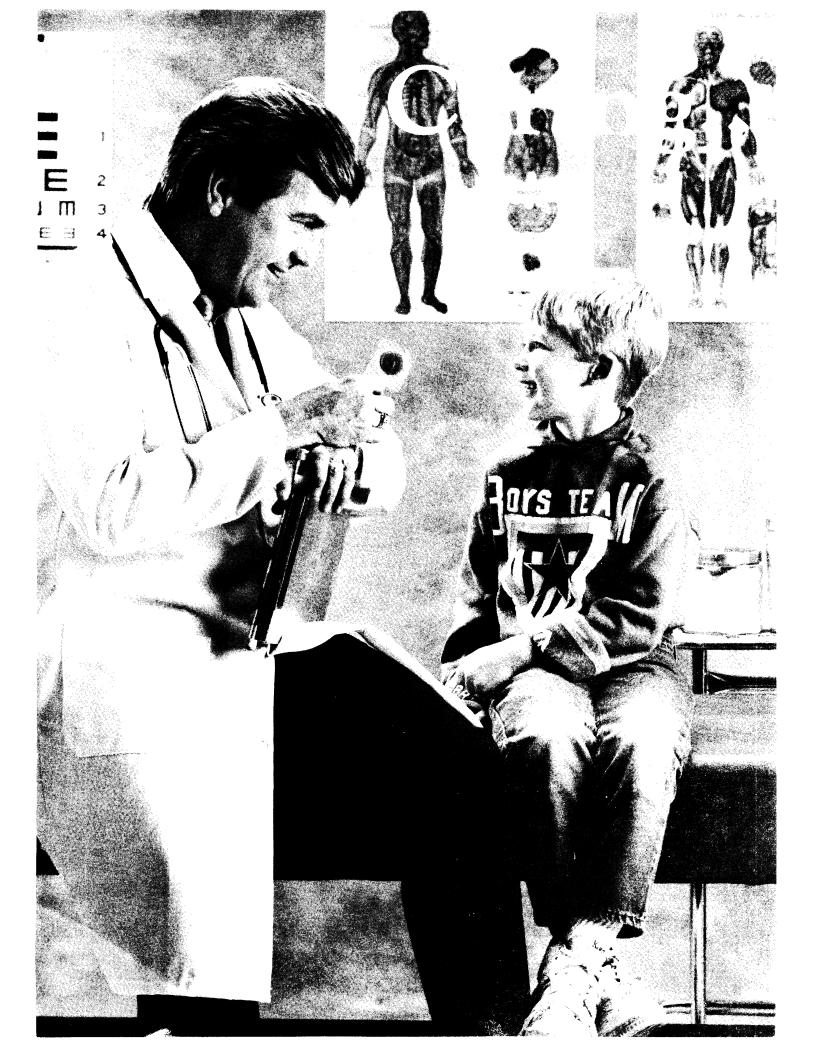
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**OB/GYN.** Multispecialty group in northwest Washington desires second Obstetrician. Excellent practice opportunity, full range of benefits, early partnership status, all practice costs paid. For more information contact Shane Spray, Administrator, 1400 E. Kincaid, Mount Vernon, WA 98273; (206) 428-2524.

SOUTH CENTRAL WYOMING. Immediate practice opportunity for BC/BE Urologist. Well-equipped JCAH hospital for a service area of approximately 20,000 population. No state or city income tax. Relocation incentives. Superior hunting, fishing, camping, snowmobiling. Three hours to Colorado ski area, five hours to Jackson Hole. One and one-half hours to the mountains. If interested, please send CV and references to D. Abels, DO, Chairman, Recruiting Committee or Richard Mills, Executive Director, Memorial Hospital of Carbon County, Rawlins, WY 82301; (307) 324-2221.



DERMATOLOGIST. Visalia Medical Clinic has an opening for a BC/BE Dermatologist now staffed by one physician who has been with the Clinic for 15 years. Located in the San Joaquin Valley in central California and population approximately 350,000. Progressive city of 62,000, near national parks and the ocean. Compensation is incentive oriented with advancement to full partnership after one year. Excellent fringe benefits. If interested, CV to John G. Heinsohn, Administrator, 5400 W. Hillsdale, Visalia, CA 93291; (209) 733-5222.

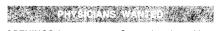
PHYSICIANS WANTED. A General Surgeon and an Oncologist to join 16 physician multispecialty group with attached 40-bed hospital located in southern Idaho. Contact Business Administrator, Box 1233, Twin Falls, ID 83301.

GENERAL PRACTICE. Busy medical center needs full-time physicians for urgent appointments. Significant evening and weekend hours. Abundant free time with no on-call responsibility. Excellent benefits and retirement program. Kaiser Permanente, Santa Teresa Hospital, 250 Hospital Pkwy, San Jose, CA 95119; (408) 972-6180.

FAMILY PRACTICE/GENERAL PRACTICE wanted for full-time practice to work three days a week and share with another Practitioner. Rural setting, good pay, nice people. Can commute for two nights a week, one hour Sacramento, one hour and 15 minutes Nevada City, two hours San Francisco. Contact Charles Rath, MD, 199 E. Webster St, Colusa, CA 95932; (916) 458-7739.

ONCOLOGIST/INTERNIST BC/BE wanted to join hospital-based multispecialty clinic near San Francisco. Complete benefit package. Send résumé to Gary Hillman, MD, Chief, Department of Medicine, Permanente Medical Group, 1150 Veterans Blvd, Redwood City, CA 94063; or call (415) 780-2626.

**GENERAL SURGEON.** Opportunity for BC/BE Surgeon with fellowship or experience in Vascular Surgery to join Surgeon in active practice in southeastern Washington state; well-equipped 71-bed hospital undergoing expansion. Send current CV to J. Griffith, PO Box 6128, Kennewick, WA 99336.



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GENERAL INTERNIST needed for large hospital-based multispecialty clinic. University associated residency program. Attractive salary and complete benefit package. Pleasant setting. BC/BE. California license required. Contact Dennis L. Ostrem, MD, Chief Internal Medicine, The Permanente Medical Group, Inc, PO Box 254999, Sacramento, CA 95865-4999 or call (916) 973-5781. An Equal Opportunity Employer.

FAMILY PRACTITIONER. Busy four physician Family Practice group (including OB) seeks replacement for partner departing fall, 1988. Located in Alaska's capital city in the Tongass National Forest offering year 'round recreation including skiing, boating, and hiking. Guaranteed salary with excellent fringe benefits and opportunity for partnership within one year. Send CV to Sarah A. Isto, MD, Valley Medical Care, Inc, 9309 Glacier Hwy, B-301, Juneau, AK 99801; (907) 789-3181.

PEDIATRICIAN, BE/BC, needed July 1988 in four-season playground. Excellent practice opportunity with positive financial success. Send CV to Dr Gerald E. Carlson, Women's Medical Clinic, 1203 10th St South, Nampa, ID 83651; (208) 467-2400.

OB/GYN, SEATTLE AREA. Rapidly growing practice seeks third OB/GYN. Come practice in a picturesque community on Puget Sound. Nearby mountains and lakes provide limitless recreational opportunities. University of Washington continuing education minutes away. For excellent incentive-oriented compensation and benefits contact Philip DuBois, MD, 7935 216th St SW, Ste E, Edmonds, WA 98020; (206) 775-0681.

ENJOY COUNTRY LIVING and outstanding year 'round outdoor recreation, excellent school system, clean environment! Join two BC Internists with growing practice in historical Wyoming community. We seek BE/BC Internist candidates recently trained or in university affiliated program. Income guarantee, paid malpractice and health insurance, more! Contact Cynthia Lacro, PROSEARCH, 305 NE 102nd Ave, Portland, OR 97220; 1 (800) 237-6906.

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Psychiatry	\$ 5,100	\$ 2,365	54%	\$ 3,789	\$ 2,052	46%
Pediatrics	7,357	2,365	68%	6,208	2,052	67%
Urology	18,571	13,735	26%	14,560	11,776	19%
Anesthesiology	19,704	13,735	30%	16,299	11,776	28%
General Surgery	30,841	17,853	42%	22,388	15,306	32%
Plastic Surgery	31,557	17,853	43%	22,961	15,306	33%
Orthopedic Surgery w/Spinal	39,744	21,971	45%	34,184	18,837	45%
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(Continued from Page 122)

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PHYSICIAN WANTED. Family Practice Physician to join 16 physician multispecialty group with attached 40-bed hospital located in southern Idaho. Contact Business Administrator, Box 1233, Twin Falls, ID 83301.

ENT PHYSICIAN, CALIFORNIA. BE/BC ENT to join staff of 14 physician multispecialty group located in the central San Joaquin Valley. Competitive starting salary and full benefits. Excellent living and practice environment. Send CV to William R. Winn, MD, Kaweah Medical Group, Inc., 222 West Willow St, Visalia, CA 93291.

WASHINGTON. Openings for career oriented Emergency Physicians, BC/BE in Emergency or Primary medical specialty. In a Seattle metropolitan hospital with 35,000 annual visits. Excellent salary with partnership potential in stable, growing group. Contact Beth Welsh at Valley Medical Center, 400 S. 43rd St, Renton, WA 98055.

PORTLAND, OREGON. Established, rapidly growing practice seeks BE/BC Internist. Multispecialty group active in private and HMO practice with satellite office. Salary and benefits first two years lead to partnership. Send CV to SMC, 10535 NE Glisan St, Portland, OR 97220, Attn: Dick Hamilton; (503) 256-0594.

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FAMILY PRACTICE PHYSICIAN WANTED. Salt Lake area family practice clinic. Close to skiing and excellent outdoor recreational opportunities. Income guaranteed and excellent benefits. Contact Robert Davis, MD, Director, Family Medical Center, 1781 West 9000 South, West Jordan, UT 84088: (801) 562-9100.

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SACRAMENTO. BC/BE Family Physicians needed for full-time primary care clinic, part-time ER/part-time primary care clinic, or full-time in our ER. We are a large-staff model HMO offering competitive salary, excellent benefit package, and shareholder status. California license required. Contact Richard Fury, MD, 1001 Riverside Ave, Roseville, CA 95678 or call (916) 784-4620. EOE.

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SAN FRANCISCO. Outstanding opportunity for BC/BE Internist, Family Practitioner, OB/GYN, or Orthopedic Surgeon at 260-bed community hospital in the dynamic South of Market area. Excellent opportunity to join busy, growing practices. Competitive salary and benefits package. Send CV to Walter Kopp, St. Luke's Hospital, 3555 Army St, San Francisco, CA 94110; (415) 641-6543.

ORTHOPEDIST, NEUROLOGIST, AND PHYSIAT-RIST one to two days per week for office-based practice specializing in evaluation and non-emergency treatment of traumatic injury patients. California license required. Medico-legal experience helpful. Fee for service, with high earning potential. CV to Director, PO Box 14046, San Francisco, CA 94114.

MONTANA. BC Family Practitioner seeks partner with interests in Obstetrics and Rural Medicine to join busy practice in southeast Montana. Office on nospital/NH campus. First year income guarantee, relocation assistance, and other benefits. Enjoy comforts of friendly small community living and recreation that only Montana can offer! Send CV to Cynthia Lacro, PROSEARCH, 305 NE 102nd Ave, Portland, OR 97220; (800) 237-6906.

SURGERY, CALIFORNIA. BE/BC General/Thoracic Surgeon to join staff of 14 physician multispecialty group located in the central San Joaquin Valley. Competitive starting salary and full benefits. Excellent living and practice environment. Send CV to William R. Winn, MD, Kaweah Medical Group, Inc., 222 West Willow St, Visalia, CA 93291.

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WOMEN'S HEALTH CENTER in Pleasanton, California seeking a Primary Care Physician. Full-time or part-time. Good salary. Lovely community 40 minutes from San Francisco. Contact Bonnie Rathjen, MD, (415) 463-3442.

FAMILY PRACTITIONERS. BE/BC for pre-paid medical group in San Francisco bay area. Send CV to James Conroy, MD, The Permanente Medical Group, Inc, 260 International Cir, San Jose, CA 95119, or call (408) 972-6339.

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WASHINGTON. Expanding physician-owned emergency group has opening for full-time career-oriented Emergency Physicians in south central Washington. Flexible work schedules, excellent working and living conditions. Send CV to EMP, PC, PO Box 805, Cheyenne, WY 82003; or contact Donald Kougl, MD, (307) 632-1436.

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BC/BE INTERNIST/FAMILY PRACTITIONER needed for growing dynamic general practice. Guaranteed salary with incentive bonuses. Full partnership available after first year. Excellent family and medical environment. Contact Donald L. Rossman, MD, 1055 W Louise Ave, Manteca, CA 95336; (209) 239-4747.

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GENERAL SURGEON—RARE OPPORTUNITY, BC/BE, to join internationally recognized Hernia Institute academically oriented. Send CV to Irving Lichtenstein, MD, c/o Lichtenstein Hernia Institute, 9201 Sunset Blvd, Ste 505, Los Angeles, CA 90069.

GENERAL INTERNIST OR BC FAMILY PRACTITIONER. Excellent opportunity to start or relocate in growing resort community in need of another physician. Hospital privilege a must. Will help a motivated individual. L. D. Lamothe, MD, 13120 Palm Dr, Desert Hot Springs, CA 92240.

VENTURA (VENTURA COUNTY). Multispecialty group of 35 physicians has immediate positions available for BC/BE General Internists. This growth oriented group is located on the California coast, 60 miles north of Los Angeles. Guaranteed salary plus incentives. Excellent benefits. No investment required. City is a great place to raise a family in a clean environment. Send résumés to Recruitment, Internist, 2705 Loma Vista Rd, Ventura, CA 93003.

SAN DIEGO, CALIFORNIA. Hospital affiliated primary care group seeking additional associates. BC/BE in Family Medicine with minor emergency skills. New state-of-the-art, outpatient primary care centers with excellent compensation package. Send CV to Medical Director, Mercy CarePoint Medical Group, 1011 Camino Del Rio South, #450(4B), San Diego, CA 92108.

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(Continued on Page 130)

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(Continued from Page 127)

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## **Rocephin** ceftriaxone sodium/Roche

Before prescribing, please consult complete product information, a summary of which follows: INDICATIONS AND USAGE: Rocephin is indicated for the treatment of the following infections when caused by susceptible organisms:

LOWER RESPIRATORY TRACT INFECTIONS caused by Strep. pneumoniae. Strepto-coccus species (excluding enterococci). Staph. aureus. H. influenzae. H. parainflu-enzae. Klebsiella species (including K. pneumoniae). E. coli, E. aerogenes, Proteus mirabilis and Serratia marcescens.

SKIN AND SKIN STRUCTURE INFECTIONS caused by Staph. aureus, Staph. epidermidis, Streptococcus species (excluding enterococci), E. cloacae, Klebsiella species (including K. pneumoniae), Proteus mirabilis and Pseudomonas aeruginosa.

URINARY TRACT INFECTIONS (complicated and uncomplicated) caused by E. coli, Proteus mirabilis, Proteus vulgaris, M. morganii and Klebsiella species (including

LINCOMPLICATED GONORRHEA (cervical/urethral and rectal) caused by Neisseria gonorrhoeae, including both penicillinase and nonpenicillinase producing strains
PELVIC INFLAMMATORY DISEASE caused by N. gonorrhoeae.

BACTERIAL SEPTICEMIA caused by Staph. aureus, Strep. pneumoniae, E. coli, H. influenzae and K. pneumoniae

BONE AND JOINT INFECTIONS caused by Staph. aureus, Strep. pneumoniae, Streptococcus species (excluding enterococci), E. coli, P. mirabilis, K. pneumoniae and Enterobacter species.

INTRA-ABDOMINAL INFECTIONS caused by E. coli and K. pneumoniae

MENINGTIS caused by H. influenzae, N. meningtidis and Strep. pneumoniae. Ceftraxone has also been used successfully in a limited number of cases of meningitis and shunt infections caused by Staph. epidermidis and E. coli.

shuft infections caused by Staph. epidermials and E. coil.

SURGICAL PROPHYLAKIS: Preoperative administration of a single 1 gm dose may reduce incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated (e.g., vaginal or abdominal hysterectomy) and in those for whom infection at the operative site presents serious risk (e.g., during coronary artery bypass surgery).

Although ceftriaxone has been shown to have been as effective as celazolin in the presented of the stable following expenses artery to polescape controlled trails.

Although certifiaxone has been shown to make been as ellective as celazonin in the pre-vention of infection following coronary artery bypass surgery, no placebe-controlled trials have been conducted to evaluate any cephalosporin antibotic in the prevention of infec-tion following coronary artery bypass surgery. When administered before indicated sur-gical procedures, a single 1 gm dose provides profection from most infections due to susceptible organisms for duration of procedure.

SUSCEPTIBILITY TESTING. Before instituting treatment with Rocephin, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing

CONTRAINDICATIONS: Rocephin is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

cephalosporin class of antibotics.

WARNINGS: BEFORE THERAPY WITH POCEPHIN IS INSTITUTED. CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS. PENICILLINS OR OTHER PRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLINS SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY. PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad-spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may Ireatment with broad-spectrum antibiotics alters the normal liora of the colon and may permit overgrowth of clostroida Studies indicate a toxin produced by Clostridium difficile is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind to the toxin in vitro. Micl cases of colitis respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte and protein supplementation as indicated

When the collisis is not relieved by drug discontinuance or when it is severe, oral vanco-mycin is the treatment of choice for antibiotic-associated pseudomembranous colitis pro-duced by C. difficile. Other causes of colitis should also be considered.

Barely, shadows suggesting sludge have been detected by sonograms of the gallblad-der in asymptomatic and symptomatic patients. This appears to be reversible on discon-tinuation of therapy. In a few symptomatic patients receiving higher than usual doses, who underwent surgery, sludge containing traces of cefficiaxone was recovered from sur-gical specimens. Discontinue therapy in patients who develop signs or symptoms suggestive of gallbladder disease, consider conservative management.

Suggestive or galiobaccer disease, consider conservative management.

PRECAITIONS: GENERAL: Although transient elevations of BLN and serum creatinine have been observed; at the recommended dosages, the nephrotoxic potential of Rocephin is similar to that of other cephalosporins.

Ceftriaxone is excreted via both biliary and renal excretion (see Clinical Pharmacology). Therefore, patients with renal failure normally require no adjustment in dosage when usual doses of Rocephin are administered, but concentrations of drug in the serum should be monitored periodically. If evidence of accumulation exists, dosage should be de-

Dosage adjustments should not be necessary in patients with hepatic dysfunction; how

Dosage adjustments should not be necessary in patients with nepatic dysfunction, nowever, in patients with both hepatic dysfunction and significant renal disease. Rocephin
dosage should not exceed 2 gm daily without close monitoring of serum concentrations.
Alterations in prothrombin times have occurred rarely in patients treated with Rocephin
Patients with impaired vitamin K synthesis or low vitamin K stores (e.g., chronic hepatic
disease and malnutrition) may require monitoring of prothrombin time during Rocephin
treatment. Vitamin K administration (10 mg weekly) may be necessary if the prothrombin
time is prolonged before or during therapy.

Prolonged use of Rocephin may result in overgrowth of nonsusceptible organisms Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Rocephin should be prescribed with caution in individuals with a history of gastrointes tinal disease, especially colitis

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Carcinogenesis. Considering the maximum duration of treatment and the class of the compound, carcinogenicity studies with ceftriaxone in animals have not been performed. The maximum

## ROCEPHIN® (ceftriaxone sodium/Roche)

duration of animal toxicity studies was six months

Mutagenesis Genetic toxicology tests included the Ames test, a micronucleus test and a test for chromosomal aberrations in human lymphocytes cultured *in vitro* with celtriaxone Celtriaxone showed no potential for mutagenic activity in these studies

Impairment of Fertility Celtriaxone produced no impairment of fertility when given intravenously to rats at daily doses up to 586 mg/kg/day, approximately 20 times the recommended clinical dose of 2 gm/day

PREGNANCY Teratogenic Effects Pregnancy Category B Reproductive studies have been performed in mice and rats at doses up to 20 times the usual human dose and have no evidence of embryoloxicity felotoxicity or teratogenicity in primates no embryoloxicity or teratogenicity was demonstrated at a dose approximately three times the human dose There are, however, no adequate and well-controlled studies in pregnant women Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Nonteralogenic Effects. In rats, in the Segment I (fertility and general reproduction) and Segment III (perinatal and postnatal) studies with intravenously administered celtriax-one, no adverse effects were noted on various reproductive parameters during gestation and lactation, including postnatal growth, functional behavior and reproductive ability of the offspring, at doses of 586 mg/kg/day or less.

NURSING MOTHERS. Low concentrations of celtriaxone are excreted in human milk

Caution should be exercised when Rocephin is administered to a nursing woman

PEDIATRIC USE: Salety and effectiveness of Rocephin in neonates, infants and children have been established for the dosages described in the Dosage and Administration section. In vitro studies have shown ceftriexone, like some other cephalosporins, can displace bilirubin from serum albumin. Exercise caution before administration to hyper-bilirubinemic neonates, especially prematures.

ADVERSE REACTIONS: Rocephin is generally well tolerated. In clinical trials, the following adverse reactions, which were considered to be related to Rocephin therapy or of uncertain etiology, were observed

LOCAL REACTIONS - pain, induration or tenderness at the site of injection (1%) Less frequently reported (less than 1%) was phlebitis after I V administration

HYPERSENSITIVITY rash (17%) Less frequently reported (less than 1%) were pruritus.

HEMATOLOGIC — eosinophilia (6%), thrombocytosis (51%) and leukopenia (21%) Less frequently reported (less than 1%) were anemia, neutropenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time

GASTROINTESTINAL -- diarrhea (2 7%) Less frequently reported (less than 1%) were nausea or vomiting, and dysgeusia

HEPATIC—elevations of SGOT (31%) or SGPT (33%) Less frequently reported (less

than 1%) were elevations of alkaline phosphatase and bilirubin

RENAL—elevations of the BUN (12%) Less frequently reported (less than 1%) were elevations of creatinine and the presence of casts in the urine

CENTRAL NERVOUS SYSTEM—headache or dizziness were reported occasionally (less than 1%)

GENITOURINARY—moniliasis or vaginitis were reported occasionally (less than 1%) MISCELLANEOUS - diaphoresis and flushing were reported occasionally (less than

Other rarely observed adverse reactions (less than 0.1%) include leukocytosis, lymphocytosis, monocytosis, basophilia, a decrease in the prothrombin time, jaundice, gallbladder sludge, glycosuria, hematuria, anaphylaxis, bronchospasm, serum sickness, abdominal pain, colitis, llatulence, dyspepsia, palpitations and epistaxis.

DOSAGE AND ADMINISTRATION: Rocephin may be administered intravenously or intramus-cularly. The usual adult daily dose is 1 to 2 gm given once a day (or in equally divided doses twice a day) depending on the type and severity of the infection. The total daily dose should not exceed 4 grams

For the treatment of serious miscellaneous infections in children, other than meningitis, the recommended total daily dose is 50 to 75 mg/kg (not to exceed 2 grams), given in divided doses every 12 hours.

Generally. Rocephin therapy should be continued for at least two days after the signs and symptoms of infection have disappeared. The usual duration is 4 to 14 days, in complicated infections longer therapy may be required.

In the treatment of meningitis, a daily dose of 100 mg/kg (not to exceed 4 grams), given in divided doses every 12 hours, should be administered with or without a loading dose

For the treatment of uncomplicated gonococcal infections, a single intramuscular dose

For preoperative use (surgical prophylaxis), a single dose of 1 gm administered 1/2 to 2 hours before surgery is recommended. When treating infections caused by Streptococcus pyogenes, therapy should be contin-

ued for at least ten days

No dosage adjustment is necessary for patients with impairment of renal or hepatic function, however, blood levels should be monitored in patients with severe renal impairment (e.g., dialysis patients) and in patients with both renal and hepatic dysfunctions

HOW SUPPLIED: Rocephin (cettriaxone sodium/Roche) is supplied as a sterile crystalline powder in glass vials and piggyback bottles. The following packages are available:

Vials containing 250 mg, 500 mg, 1 gm or 2 gm equivalent of celtriaxone, piggyback bottles containing 1 gm or 2 gm equivalent of celtriaxone, bulk pharmacy containing 10 gm equivalent of celtriaxone (NOT FOR DIRECT ADMINISTRATION)

Also supplied as a sterile crystalline powder as follows.

ADD-Vantage Vials\*\* containing 1 gm or 2 gm equivalent of ceftriaxone.

Also supplied premixed as a frozen iso-osmotic, sterile, nonpyrogenic solution of ceftriaxone sodium in 50 mL, single dose plastic containers. Tas follows:

1 gm equivalent of ceftriaxone, iso-osmotic with approximately 1 g gm dextrose hydrous. USP added

2 gm equivalent of ceftriaxone, iso-osmotic with approximately 12 gm dextrose hydrous, USP added.

NOTE: Rocephin in the frozen state should not be stored above -20°C

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†Manufactured for Roche Laboratories, Division of Hoffmann-La Roche Inc., by Travenol Laboratories, Inc., Deerfield, Illinois 60015



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## Once-a-day Rocephin Roche Ceftriaxone sodium/Roche

Please see adjacent page for summary of product information.

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